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BRISTOL, LYNN ANNE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,556	LEDBETTER ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Both Claims 57 and 58 are duplicates of Claims 59 and 60, respectively. Claims 59 and 60 have been withdrawn from restriction.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   1. Claims 1-36, 37 in part, 38-58, 61-75, drawn to synthetic scFv polypeptides (i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to a drug, classified in class 530, subclass 387.3.
   2. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to a toxin, classified in class 530, subclass 387.3.
   3. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to an immunomodulator, classified in class 536, subclass 387.3.
   4. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to a polypeptide effector, classified in class 530, subclass 387.3.
   5. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to an isotope, classified in class 536, subclass 387.3.

6. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to a label, classified in class 536, subclass 387.3.

7. Claims 1-36, 37 in part, 38-58, and 61-75, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide; ii) linker; iii) Ig CH) coupled to an effector moiety, classified in class 536, subclass 387.3.

8. Claim 76 and 109, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide comprising VH with amino acid modifications at positions 9-12, 108, 110, 112; ii) linker; iii) Ig CH), classified in class 536, subclass 387.3.

9. Claim 82, drawn to synthetic scFv polypeptides ((i) binding domain polypeptide comprising VH with serine substitution for leucine at position 11; ii) IgA hinge region; iii) Ig CH), classified in class 536, subclass 387.3.

10. Claim 83, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) amino acid substituted connector; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

11. Claim 84, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) IgA hinge; iii) IgA CH2 and CH3 comprising CH3 amino acid deletions or substitutions), classified in class 536, subclass 387.3.

12. Claim 85, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third

cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitution position 322), classified in class 536, subclass 387.3.

13. Claim 86, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitution position 322), classified in class 530, subclass 387.3.

14. Claim 87, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitution position 331), classified in class 530, subclass 387.3.

15. Claim 88, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitution position 331), classified in class 530, subclass 387.3.

16. Claim 89, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1

CH2 and CH3 comprising CH2 amino acid substitution position 256), classified in class 530, subclass 387.3.

17. Claim 90, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) 2H7 scFv CH2 and CH3 from IgG1 comprising CH2 amino acid substitutions at positions 255-258), classified in class 530, subclass 387.3.

18. Claim 91, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitutions at position 290), classified in class 530, subclass 387.3.

19. Claim 92, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3 comprising CH2 amino acid substitutions at position 339), classified in class 536, subclass 387.3.

20. Claim 93, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

21. Claim 94, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

22. Claim 95, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising second cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

23. Claim 96, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising first and second cysteine residue substitutions; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

24. Claim 97, drawn to synthetic scFv polypeptides ((i) scFv binding domain from FC2-2 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

25. Claim 98, drawn to synthetic scFv polypeptides ((i) scFv binding domain from UCHL-1 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

26. Claim 99, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 5B9 hybridoma; ii) connector comprising first, second and third

cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

27. Claim 100, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 2H7 hybridoma; ii) connector comprising first, second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

28. Claim 101, drawn to synthetic scFv polypeptides ((i) scFv binding domain from 5B9 hybridoma; ii) connector comprising second and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

29. Claim 102, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising first and third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

30. Claim 103, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising third cysteine residue substitutions and proline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

31. Claim 104, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) connector comprising first cysteine residue substitutions; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

32. Claim 105, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) murine IgA hinge region; iii) murine IgA CH2 and CH3 comprising four amino acid deletions/substitutions in the CH3), classified in class 536, subclass 387.3.

33. Claim 106, drawn to synthetic scFv polypeptides ((i) scFv binding domain from G28-1 hybridoma; ii) human IgA hinge region; iii) human IgA CH2 and CH3 comprising four amino acid deletions/substitutions in the CH3), classified in class 536, subclass 387.3.

34. Claim 107, drawn to synthetic scFv polypeptides ((i) scFv binding domain from HD37 hybridoma; ii) connecting region comprising first, second and third cysteine residue substitutions and praline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

35. Claim 108, drawn to synthetic scFv polypeptides ((i) scFv binding domain from L6; ii) connecting region comprising first, second and third cysteine residue substitutions and praline residue substitution; iii) IgG1 CH2 and CH3), classified in class 536, subclass 387.3.

3. Claims 77-81 links inventions of Claims 82-108. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, Claims 77-81. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from

or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP § 804.01.

4. The inventive groups are distinct and separate for the following reasons:

Inventions of Groups 1-35 represent separate and distinct products, which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polypeptide scFv products are distinct in that each would contain different amino acids which occur naturally or are introduced by mutation, and the products could be generated by synthetic means or subcloning the cDNAs encoding the different fragments (i.e., domains, regions, connectors, etc.) so that the cDNAs are operatively linked for co-expression of an mRNA. The polypeptides would be made by translation of mRNA, and the mRNA would differ for each of the respective scFv polypeptides.

Furthermore, Groups 1-7differ from Groups 8-35 in that the scFvs are coupled to other molecules, and this coupling does not require the co-expression of the scFv with the coupled entity, rather, the coupling can occur by chemical corss-linking, antibody cross-linking, avidin-biotin crosslinking, etc.

The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions of Groups 1-35 are patentably distinct.

4. Additionally, searching all of the groups would pose a serious burden on the examiner because a) these inventions are distinct for the reasons given above; b) they have acquired a separate status in the art because of their recognized divergent subject matter, and c) the inventions of Groups 1-35 require different searches that are not co-extensive, therefore restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. If any one of Groups 1-7 is elected, then species (position 11 amino acid substitution for scFv CH) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) serine

Specie B) threonine

Specie C) cysteine

Specie D) tyrosine

Specie E) asparagines

Specie F) glutamine

Specie G) aspartic acid

Specie H) glutamic acid

Specie I) lysine

Specie J) arginine

Specie K) histidine

Species A-K represent individual amino acids that when substituted or deleted from any given protein domain, would result in any number of chemical, structural and biological changes for the protein molecule. It is well established in the art, that even conservative amino acid substitutions can have unpredictable and profound effects on folding of proteins compared to their native or wild-type forms. Consequently, any amino acid substitution or deletion which affects the inherent internal binding or folding properties of a protein within it self much less the external binding or folding of the protein with other proteins such as protein subunits in a complex, metals, ligands, receptors, etc, would be unpredicatable to one of ordinary skill in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A-K.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the amino acids having obtained a separate status in the art.

7. If any of Groups 1-7 is elected, then species (B cell antigen) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

A1) CD19

B1) CD20

C1) CD 22

D1) CD 37

E1) CD 40

F1) CD 80

G1) CD 86

The species of B cell antigen A1-G1 are each distinct. One of skill in the art would readily appreciate that each of the species has unique chemical, structural, biological, tissue distribution and disease correlates, and that these properties for any of the species are known and described in any commercially available table of Cluster of Differentiation Antigens or by referring to the Human Protein Reference Database (www.hprd.org).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A1-G1.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the B cell antigens having obtained a separate status in the art.

8. If any of Groups 1-7 is elected, then species (single chain Fv) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

A2) HD37

B2) 2H7

C2) G28-1

D2) FC2-2

E2) UCHL-1

F2) 5B9

G2) L6

H2) 10A8

I2) 2e12

J2) 40.2.36

K2) G19-4

L2) 1D8

M2) 4.4.220

The species of scFv are each distinct. These scFv are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: each of the scFv is produced by a different hybridoma. Each scFv has a unique amino acid sequence, each scFv binds to a different epitope and each scFv has its own unique ability to stimulate an immune response and/or binding affinity to an antigen or epitope.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 32 are generic as to species A2 and M2.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the hybridomas having obtained a separate status in the art.

9. If any of Groups 1-7 is elected, then species (target) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A3) CD 2

Specie B3) CD3

Specie C3) CD4

Specie D3) CD5

Specie E3) CD6

Specie F3) CD8

Specie G3) CD10

Specie H3) CD11b

Specie I3) CD14

Specie J3) CD20

Specie K3) CD 21

Specie L3) CD 22

Specie M3) CD 23

Specie N3) CD 24

Specie O3) CD 25

Specie P3) CD 28

Specie Q3) CD 30

Specie R3) CD 37

Specie S3) CD40

Specie T3) CD 43

Specie U3) CD 50 (ICAM3)

Specie V3) CD 54 (ICAM1)

Specie W3) CD 56

Specie X3) CD 69

Specie Y3) CD 80

Specie Z3) CD 86

Specie AA3) CD 134 (OX40)

Specie BB3) CD 137 (41BB)

Specie CC3) CD 152 (CTLA-4)

Specie DD3) CD 153 (CD30 ligand)

Specie EE3) CD 154 (CD 40 ligand)

Specie FF3) ICOS

Specie GG3) L6

Specie HH3) B7-H1

Specie II3) HLA class II

Species A3-II3 are each distinct. These target antigens are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: One of skill in the art would readily appreciate that each of the species has unique chemical, structural, biological, tissue distribution and disease correlates, and that these properties for any of the species are known and described in any commercially available table of Cluster of Differentiation Antigens or by referring to the Human Protein Reference Database (www.hprd.org).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A3-II3.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the target molecules having obtained a separate status in the art.

10. If any of Groups 1-7 is elected, then species (immunological activity) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A4) antibody dependent cell-mediated toxicity

Specie B4) complement fixation

Specie C4) induction of apoptosis

Specie D4) induction of biologically active signals

Specie E4) induction of immune effector cells

Specie F4) activation of cellular differentiation

Specie G4) cellular activation

Specie H4) release of biologically active molecules

Specie I4) neutralization of an infection agent or toxin

Species A4-I4 are each distinct. These immunological activities are considered to be unrelated, since each is functionally independent and distinct for the following reasons: One of skill in the art would readily appreciate that each of the species is associated with different arms of the immune response (humoral, cellular, complement), thus involving different growth factors, soluble mediators, antibodies, complement, etc., and that the properties for any of the species are known and described in any commercially available immunology textbook ("Cellular and Molecular Immunology" by Abul Abas, Andrew Lichtman and Jordan Pober 4th Ed. 2000; "Immunobiology: the immune system in health and disease" by Charles Janeway, Jr. and Paul Travers, 5th Ed. 2001).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A4-I4.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the immunological activities having obtained a separate status in the art.

11. If any of Groups 1-7 is elected, then species (biologically active signals) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A5) protein kinases

Specie B5) protein phosphatses

Specie C5) G-proteins

Specie D5) cyclic nucleotides

Specie E5) second messengers

Specie F5) ion channels

Specie G5) secretory pathway components

Species A4-I4 are each distinct. These biologically active signaling molecules are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: One of skill in the art would readily appreciate that each of the species is associated with different pathways in mediating cellular signal transduction, and that the properties for any of the species are known and described in any commercially available signal transduction textbook ("Biochemistry of Signal Transduction and Regulation" by Gerhard Krauss; "Biochemistry of Cell Signaling" by Ernst J. M. Helmreich).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A5-G5.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the signal transducing molecules having obtained a separate status in the art.

12. If any of Groups 1-7 is elected, then species (immune effector cells) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A6) NK cells

Specie B6) monocytes

Specie C6) B cells

Specie D6) T cells

Specie E6) mast cells

Specie F6) neutrophils

Specie G6) eosinophils

Specie H6) basophils

Species A4-I4 are each distinct. These immune effector cells are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: see interpretation under section 10, *supra*.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A6-H6.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the immune effector cells having obtained a separate status in the art.

13. If any of Groups 1-7 is elected, then species (cytokine) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A7) monokines

Specie B7) lymphokines

Specie C7) chemokines

Specie D7) growth factor

Specie E7) colony stimulating factors

Specie F7) interferons

Specie G7) interleukins

Species A7-G7 are each distinct. These cytokines are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: see interpretation under sections 9 and 10, *supra*, in addition to one of skill in the art having access to the commercially available cytokine database, www.copewith cytokines).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A7-G7.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the cytokines having obtained a separate status in the art.

13. If any of Groups 1-7 is elected, then species (infectious agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A8) bacterium

Specie B8) virus

Specie C8) parasite

Specie D8) fungus

Species A8-D8 are each distinct. These infectious agents are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: one of skill in the art would readily appreciate that each of the species represent distinct and separate microorganisms that are unrelated by genus or species, and that information about the properties for each of the genus of can be accessed through any commercially available microbiology textbook ("Textbook of Microbiology" by William Burroughs).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A8-D8.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the infectious agents having obtained a separate status in the art.

14. If any of Groups 1-7 is elected, then species (exotoxin) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A9) anthrax toxin

Specie B9) cholera toxin

Specie C9) diphtheria toxin

Specie D9) pertussis toxin

Specie E9) E. coli heat labile toxin LT

Specie F9) E. coli heat stable toxin ST

Specie G9) shiga toxin

Specie H9) Pseudomonas exotoxin A

Specie I9) botulinum toxin

Specie J9) Bordetella pertussis AC toxin

Specie K9) Bacillus antracis EF

Species A9-K9 are each distinct. These exotoxins are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: the toxin species do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any reference manual (e.g., Merck Index) or a microbiology textbook describing the structure, solubility characteristics, biological properties, and would appreciate that based on these reference disclosures alone or in combination, that these species are distinct and separate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A9-K9.

Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the exotoxins having obtained a separate status in the art.

15. If any of Groups 1-7 is elected, then species (endotoxin) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A10) saxitoxins

Specie B10) tetrodotoxin

Specie C10) mushrooms toxins

Specie D10) aflatoxins

Specie E10) pyrrolizidine alkaloids

Specie F10) phytohemagglutinins

Specie G10) grayanotoxins

Species A10-G10 are each distinct. These endotoxins are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: the toxin species do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any

reference manual (e.g., Merck Index) or a microbiology textbook describing the structure, solubility characteristics, biological properties, and would appreciate that based on these reference disclosures alone or in combination, that these species are distinct and separate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A10-G10.

Additionally, searching all of the endotoxin species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the endotoxins having obtained a separate status in the art.

16. If any of Groups 1-7 is elected, then species (species of binding domain) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A11) human

Specie B11) murine

Specie C11) rat

Specie D11) pig

Specie E11) monkey

Species A11-E11 are each distinct. These species of binding domain are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: see interpretation under sections 9 and 10 *supra*, as the comments relate to antibodies and immunoglobulin structures.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A11-E11.

Additionally, searching all of the species of binding domain species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the binding domain having obtained a separate status in the art.

17. If any of Groups 1-7 is elected, then species (hinge region) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A12) human hinge

Specie B12) human IgG hinge

Specie C12) human IgA hinge

Specie D12) human IgE hinge

Specie E12) camelid hinge

Specie F12) llama hinge

Specie G12) nurse shark hinge

Specie H12) spotted ratfish hinge

Species A12-H12 are each distinct. These species of hinge region are considered to be unrelated, since each is structurally and functionally independent and distinct for the following reasons: see interpretation under sections 9 and 10 *supra*, as the comments relate to antibodies and immunoglobulin structures.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic as to species A12-H12.

Additionally, searching all of the species of hinge region would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the hinge regions having obtained a separate status in the art.

18. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LAB

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